

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

OTSUKA PHARMACEUTICAL CO.,
LTD.,

Plaintiff,

v.

MYLAN INC., MYLAN
PHARMACEUTICALS INC., and
MYLAN LABORATORIES LIMITED,

Defendants.

HONORABLE JEROME B. SIMANDLE

Civil Action
No. 14-4508 (JBS/KMW)

OPINION

APPEARANCES:

Melissa A. Chuderewicz, Esq.
PEPPER HAMILTON LLP
301 Carnegie Center
Princeton, N.J. 08543

-and-

James B. Monroe, Esq.
Paul W. Browning, Esq.
Denise Main, Esq.
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
901 New York Avenue, N.W.
Washington, D.C. 20001-4413
Attorneys for Plaintiff

Arnold B. Calmann, Esq.
Jeffrey Soos, Esq.
Katherine A. Escanlar, Esq.
SAIBER LLC
One Gateway Center, 10th Floor
Newark, N.J. 07102

-and-

Deepro R. Mukerjee, Esq.
Lance A. Soderstrom, Esq.
James C. Grant, Esq.
Jonathan D. Parente, Esq.
ALSTON & BIRD LLP
90 Park Avenue
New York, N.Y. 10016
Attorneys for Defendant

SIMANDLE, Chief Judge:

Table of Contents

I. INTRODUCTION	2
II. BACKGROUND	5
III. STANDARD OF REVIEW	10
IV. DISCUSSION	11
A. Federal Circuit Law Governs the Court's Resolution of the Jurisdictional Issue	11
B. Personal Jurisdiction, Generally	12
1. Whether Mylan is "at home" in New Jersey for Purposes of General Jurisdiction after <u>Daimler</u>	14
2. Mylan Inc. and Mylan Pharma Consented to Personal Jurisdiction in this District by Registering to do Business in New Jersey	23
3. The Court Lacks Specific Jurisdiction over Mylan Labs .	33
V. CONCLUSION	35

I. INTRODUCTION

This patent infringement action is one of twenty-four related actions concerning various defendants' submission of abbreviated new drug applications (hereinafter, "ANDAs") for Food and Drug Administration (hereinafter, "FDA") approval to market generic versions of Plaintiff Otsuka Pharmaceutical Co., Ltd.'s (hereinafter, "Otsuka") aripiprazole product known as Abilify®. Defendants Mylan Inc., Mylan Pharmaceuticals Inc. ("Mylan Pharma") and Mylan Laboratories Limited ("Mylan Labs")

and collectively, "Mylan") move to dismiss Otsuka's Complaint for lack of personal jurisdiction.¹ [Docket Item 15.]

Mylan Inc., "one of the world's leading generic and specialty companies," and its subsidiaries, Mylan Pharma and Mylan Labs, specifically argue that Mylan lacks any claim-related or jurisdiction-conferring contacts to New Jersey. (See, e.g., Mylan's Reply at 1-10.) Otsuka counters, however, that Mylan's substantial connections with this forum readily enable this Court to exercise personal jurisdiction over each Mylan entity. (See, e.g., Otsuka's Opp'n at 9-19.) Otsuka, in particular, argues that Mylan's compliance with the State of New Jersey's foreign corporation licensing and registration statute constitutes consent to this Court's jurisdiction; that Mylan's future intent to market and distribute its generic products in New Jersey suffices for purposes of specific jurisdiction; and that Mylan's compliance with licensing and/or registration requirements, revenue generation, and related activities otherwise constitute "continuous and systematic" contacts with this forum for purposes of general jurisdiction. (See, e.g., id.)²

¹ Of the over 30 defendants involved in these related actions, only the Mylan Defendants have challenged this Court's personal jurisdiction.

² Otsuka filed a sur-reply together with an informal request for leave [Docket Item 38], which Mylan opposes as improper under the Local Civil Rules. [Docket Item 42.] Despite Mylan's objection, given the complexity of the jurisdictional issues

Mylan does not dispute that each of its entities complies with the statutory registration requirements of the State of New Jersey, that each of its entities holds a wholesale distribution license in the State of New Jersey, nor that each of its entities generate revenue attributable to sales in the State of New Jersey. (See Tighe Dec. at ¶¶ 8, 9, 11; Tighe Supplemental Dec. at ¶ 2.) Rather, Mylan disputes whether this quantum of connections suffices for purposes of personal jurisdiction, given the Supreme Court's "sea-change" jurisdictional decision in Daimler AG v. Bauman, 134 S. Ct. 746 (2014), and because Mylan maintains no corporate offices, facilities, nor records in this State. (See, e.g., Mylan's Br. at 5-11; Mylan's Reply at 1-10.)

The primary issues before the Court are whether the record demonstrates that the Mylan Defendants' contacts with this forum render them "at home" in the State of New Jersey; whether Mylan's registration to do business in New Jersey and appointment of an in-state agent for service of process amount to consent to this Court's jurisdiction; and whether, in submitting an ANDA for FDA approval, the Mylan Defendants purposefully directed activities at this forum.

For the reasons that follow, the Court finds that this Court may exercise general jurisdiction over Mylan Inc. and

involved in the pending motion, the Court will grant Otsuka's informal request, and will consider Otsuka's sur-reply.

Mylan Pharma. Because Mylan Labs, however, lacks sufficient jurisdictional contacts with this forum, Mylan Labs will be dismissed. Mylan's motion will, accordingly, be denied with respect to Mylan Inc. and Mylan Pharma, but granted with respect to Mylan Labs.

II. BACKGROUND

A. Otsuka and New Drug Application No. 21-436

Otsuka, a pharmaceutical company organized and existing under the laws of Japan, holds New Drug Application (hereinafter, "NDA") No. 21-436, approved by the FDA, for aripiprazole tablets, which Otsuka markets under the trademark Abilify®. (See Compl. at ¶¶ 1, 16-17.)

In connection with Abilify's® listing in the Orange Book, the FDA's book of drug products approved under the Food, Drug, and Cosmetic Act (hereinafter, the "Orange Book"), 21 U.S.C. § 355(j), Otsuka identifies the following patents: U.S. Patent Nos. 8,017,615 ("the '615 patent"), 8,580,796 ("the '796 patent"), 8,642,760 ("the '760 patent"), 7,053,092 ("the '092 patent") and 8,642,600 ("the '600 patent"), all of which Otsuka owns by virtue of assignment. (See id. at ¶¶ 5, 13, 17, 27, 30, 37, 40, 47, 50, 57, and 60.)

B. Mylan Inc., Mylan Pharma, and Mylan Labs

As stated above, the pending motion concerns the jurisdictional contacts of three Mylan entities: Mylan Inc. and its two subsidiaries, Mylan Pharma and Mylan Labs.

Mylan Inc., a Pennsylvania corporation having a principal place of business in Canonsburg, Pennsylvania, manufactures, markets, imports, and sells generic and specialty pharmaceutical products throughout the United States, including in New Jersey. (See id. at ¶ 2, 7; Tighe Dec. at ¶¶ 2-3, 11.) Indeed, Mylan Inc. expressly identifies itself as "one of the world's leading generic and specialty pharmaceutical companies," which "markets more than 1,300 different products in around 140 different countries and territories" (Tighe Dec. at ¶ 3), and "holds the number one ranking in the U.S. generics prescription market in terms of sales and the number two ranking in terms of prescriptions dispensed." (Compl. at ¶ 7; see also Ex. A to Otsuka's Opp'n.)

In 2006, the State of New Jersey authorized Mylan Inc. to "transact business" as a "foreign profit corporation" pursuant to N.J.S.A. §§ 14A:13-4, 14-1, -2. (See Ex. F to Otsuka's Opp'n.) In connection with New Jersey's authorization, Mylan Inc. identified its registered office and designated an in-state agent for service process of process. (See Tighe Dec. at ¶ 8 (noting Mylan Inc.'s compliance with statutory registration requirements); Ex. F to Otsuka's Opp'n (identifying an agent in

West Trenton, New Jersey).) In addition to being registered in New Jersey, Mylan holds a wholesale distribution license, and generates annual revenues in excess of \$100 million in this State. (See Tighe Dec. at ¶ 11.) Finally, Mylan Inc. has actively litigated, as both plaintiff and defendant, over 30 cases in this District. (See Ex. K to Otsuka's Opp'n (summarizing the cases).) Nevertheless, Mylan Inc. maintains no permanent, physical presence in the State of New Jersey.

Mylan Inc.'s subsidiary, Mylan Pharma serves as Mylan Inc.'s "primary U.S. pharmaceutical research, development, manufacturing, marketing and distribution subsidiary." (Tighe Dec. at ¶ 4; Ex. A to Otsuka's Opp'n; Compl. at ¶ 8.) Like its corporate parent, however, Mylan Pharma "does not have any manufacturing plants, corporate offices, facilities, or other real property in New Jersey." (Tighe Dec. at ¶ 6.) Rather, Mylan Pharma exists and operates in the State of West Virginia. (See generally id.) Nevertheless, Mylan Pharma has registered to do business in New Jersey and has appointed an in-state agent for service of process. (See Ex. G to Otsuka's Opp'n.) In addition, Mylan Pharma holds a wholesale distribution license in New Jersey, and generates annual revenues in excess of \$50 million in this State. (Tighe Dec. at ¶¶ 9, 11; Tighe Supplementary Dec. at ¶ 2.) Finally, Mylan Pharma has been an equally active litigant in this District, having litigated over

30 cases, as both plaintiff and defendant. (See Ex. K to Otsuka's Opp'n (summarizing the cases).)

Mylan Labs, Mylan Inc.'s Indian subsidiary, constitutes "one of the world's largest manufacturers of active pharmaceutical ingredients (APIs)" (Compl. at ¶ 9 (citation omitted)), and manufactures and supplies "low cost, high quality API for [Mylan Inc.'s] own products and pipeline." (Ex. A to Otsuka's Opp'n.) Unlike its parent and sister corporations, however, Mylan Labs has not registered as a foreign corporation in New Jersey, nor appointed an agent for service of process. (See Tighe Dec. at ¶ 8.) Mylan Labs does, however, hold a wholesale distribution license in New Jersey, generates revenues "attributable to sales in New Jersey," and has been involved in at least three cases in this District. (Id. at ¶ 11; see also Ex. K to Otsuka's Opp'n (summarizing the cases).)

C. Mylan Pharma's ANDA Filing and ADNA Notice Letter

On November 16, 2013, Mylan Pharma submitted ANDA No. 206-240 to the FDA in Maryland, seeking approval to market generic aripiprazole tablets in the United States. (Compl. at ¶ 19.) Mylan Pharma's ANDA filing included a "paragraph IV certification" pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), in which Mylan Pharma set forth its assertion concerning the Abilify® patents' invalidity, in addition to its assertion that the Abilify® patents will not be infringed by the commercial

manufacture, use, or sale of Mylan's generic product. (See Tighe Dec. at ¶ 12.)

On May 28, 2014, Mylan Pharma then mailed notice, under 21 U.S.C. § 355(j)(2)(B)(ii), of its ANDA filing and its certification of non-infringement and/or invalidity to Otsuka Pharmaceutical Co., Ltd. in Japan and Otsuka America Pharmaceutical, Inc. in Maryland. (See Tighe Dec. at ¶ 12; see also Compl. at ¶¶ 19-21, 31, 41, 51, and 61.)

D. Otsuka's ANDA Litigation

As a result of Mylan Pharma's ANDA filing, Otsuka filed a Complaint in this District on July 11, 2014,³ alleging that Mylan Pharma's proposed generic product "will, if approved and marketed," infringe at least one claim of the '615, '796, '760, '092, and '600 Patents.⁴ (Id. at ¶¶ 22-23, 32-33, 42-43, 52-53, and 62-63.) (See generally Compl. at ¶ 5.) After Otsuka

³ At that time, Otsuka had filed six substantively identical Complaints naming other ANDA filers as defendants. See, e.g., Otsuka Pharma. Co., Ltd. v. Torrent Pharma. Ltd., Inc., Civil Act. No. 14-1078 (JBS/KMW); Otsuka Pharma. Co., Ltd. v. Alembic Pharma. Ltd., Civil Act. No. 14-2982 (JBS/KMW); Otsuka Pharma. Co., Ltd. v. Zydus Pharma. USA, Inc., Civil Act. No. 14-3168 (JBS/KMW); Otsuka Pharma. Co., Ltd. v. Aurobindo Pharma. Ltd., Civil Act. No. 14-3306 (JBS/KMW); Otsuka Pharma. Co., Ltd. v. Intas Pharma. Ltd., Civil Act. No. 14-3996 (JBS/KMW); Otsuka Pharma. Co., Ltd. v. Sun Pharma. Indus. Ltd., Inc., Civil Act. No. 14-4307 (JBS/KMW).

⁴ On March 20, 2015, Otsuka moved to amend its Complaint in order to alleged infringement of a sixth patent, U.S. Patent No. 8,759,350. [Docket Item 62.] Otsuka's motion to amend will be addressed by separate Order.

successfully effectuated service on October 1, 2014 [Docket Items 7 and 8], the pending motion followed.

III. STANDARD OF REVIEW

Federal Rule of Civil Procedure 12(b)(2) permits a party to move to dismiss a case for lack of personal jurisdiction. See FED. R. CIV. P. 12(b)(2). Where, as here, the Court resolves the jurisdictional issue in the absence of an evidentiary hearing and without the benefit of discovery, the plaintiff need only establish a prima facie case of personal jurisdiction. See Avocent Huntsville Corp. v. Aten Int'l Co., Ltd., 552 F.3d 1324, 1328-29 (Fed. Cir. 2008) (citations omitted). Therefore, the Court must "accept the uncontroverted allegations in the plaintiff's complaint as true and resolve any factual conflicts in the affidavits [and other written materials] in the plaintiff's favor." Elecs. for Imaging, Inc. v. Coyle, 340 F.3d 1344, 1349 (Fed. Cir. 2003) (citations omitted). Nevertheless, "the plaintiff bears the burden of showing the basis for jurisdiction," Graphic Props. Holdings, Inc. v. ASUS Computer Int'l, ___ F. Supp. 3d ___, No. 13-864, 2014 WL 4949589, at *2 (D. Del. Sept. 29, 2014), and must establish "with reasonable particularity sufficient contacts between the defendant and the forum state." Mellon Bank (E) PSFS, Nat'l Ass'n v. Farino, 960 F.2d 1217, 1223 (3d Cir. 1992); see also AFTG-LG, LLC v Nuvoton

Tech. Corp., 689 F.3d 1358, 1360-61 (Fed. Cir. 2012) (discussing the plaintiff's prima facie burden).⁵

IV. DISCUSSION

A. Federal Circuit Law Governs the Court's Resolution of the Jurisdictional Issue

The parties dispute the choice of law applicable to the pending motion. Mylan, in particular, insists that Federal Circuit law governs the Court's disposition of the jurisdictional issue presented in the pending motion, while Otsuka suggests that the Court must follow binding precedent of the Third Circuit. (Compare Mylan's Reply at 8 n.5, with Otsuka's Sur-reply at 1.)

The Court, however, does not find determination of the relevant choice of law to be a particularly complex inquiry. Indeed, because the pending jurisdictional issue arises in the context of a patent infringement action under the Hatch-Waxman Act, Federal Circuit law unquestionably governs the key disputed issue, namely, whether due process would be offended in the event the Court exercised personal jurisdiction over the Mylan Defendants, the "out-of-state accused infringer[s]." Nuance Commc'ns, Inc. v. Abby Software House, 626 F.3d 1222, 1230

⁵ Moreover, the Court may always revisit the issue of personal jurisdiction if later revelations reveal that the facts alleged in support of jurisdiction remain in dispute. See Metcalfe v. Renaissance Marine, Inc., 566 F.3d 324, 331 (3d Cir. 2009) (citing Carteret Sav. Bank, FA v. Shushan, 954 F.2d 141, 142 n.1 (3d Cir. 1992)).

(Fed. Cir. 2010); see also Hildebrand v. Steck Mfg. Co., Inc., 279 F.3d 1351, 1354 (Fed. Cir. 2002) ("We apply Federal Circuit law to determine whether the district court properly exercised personal jurisdiction over out-of-state defendants in patent infringement cases."); Acorda Therapeutics, Inc. v. Mylan Pharma., Inc., ___ F. Supp. 3d ___, No. 14-935, 2015 WL 186833, at *4 (D. Del. Jan. 14, 2015) (applying Federal Circuit law).⁶ Having determined the choice of law applicable to the pending motion, the Court turns to personal jurisdiction under the Federal Circuit's standard

B. Personal Jurisdiction, Generally

A federal district court may assert personal jurisdiction over a nonresident of the state in which the court sits to the extent authorized by the law of that state. See, e.g., Merial Ltd. v. Cipla Ltd., 681 F.3d 1283, 1293-94 (Fed Cir. 2012).

Therefore, under Federal Circuit law, determining "whether jurisdiction exists over an out-of-state defendant involves two inquiries: whether a forum state's long-arm statute permits service of process and whether assertion of personal

⁶ Nevertheless, in the absence of relevant Federal Circuit authority, particularly whether registration constitutes consent for jurisdictional purposes, the Court may, and necessarily must, refer to decisions of other federal courts for guidance. See Acorda Therapeutics, Inc., 2015 WL 186833, at *9 (considering decisions of other court of appeals, given the absence of Federal Circuit law); Forest Labs., Inc. v. Amneal Pharma. LLC, No. 14-508, 2015 WL 880599, *9 n.10 (D. Del. Feb 26, 2015) (same).

jurisdiction violates due process." See Autogenomics, Inc. v. Oxford Gene Tech. Ltd., 566 F.3d 1012, 1016 (Fed. Cir. 2009).

In this instance, however, because the New Jersey long-arm statute "permits the exercise of personal jurisdiction to the fullest limits of due process," IMO Indus., Inc. v. Kiekert AG, 155 F.3d 254, 259 (3d Cir. 1998), "'the two inquiries collapse'" into one: whether the exercise of jurisdiction comports with due process. Autogenomics, Inc., 566 F.3d at 1017 (citations omitted). Accordingly, a court must consider whether the "defendant has certain minimum contact with [the State] such that the maintenance of the suit does not offend 'traditional notions of fair play and substantial justice.'" Daimler, 134 S. Ct. at 754 (2014) (quoting Goodyear Dunlop Tires Operations, S.A. v. Brown, 131 S. Ct. 2846, 2853 (2011)).

Sufficient jurisdictional contacts, in turn, arise in two forms: general and specific. Daimler, 134 S. Ct. at 754. General jurisdiction, on one hand, generally requires that the defendant's contacts be "so 'continuous and systematic' as to render them essentially at home in the forum State.'" Id. Specific jurisdiction, on the other hand, requires that the suit "'arise out of or relate to the defendant's [specific] contacts with the forum.'" Id. (quoting Helicopteros Nacionales de Colombia, S.A. v. Hall, 466 U.S. 408, 414 n.8 (1984)).

Otsuka asserts three ground for this Court's exercise of personal jurisdiction over the Mylan Defendants: (1) general jurisdiction, notwithstanding Daimler; (2) general jurisdiction based upon consent; and (3) specific jurisdiction. The Court will address each argument in turn.

1. Whether Mylan is "at home" in New Jersey for Purposes of General Jurisdiction after Daimler

Otsuka first claims that the Mylan Defendants numerous contacts with this forum suffice to subject each Mylan Defendant to the general personal jurisdiction of this Court. (See, e.g., Otsuka's Opp'n at 18-20.) The Mylan Defendants, however, claim that their contacts plainly fail to render them "'essentially at home'" in this forum. (Mylan's Br. at 3-5.) Indeed, Mylan argues that its activities in this forum amount to little more than the sort of activities the Supreme Court deemed insufficient in Daimler. (Id. at 3-6.) Here, for the reasons that follow, the Court determines that Daimler fundamentally altered the general jurisdiction analysis, but need not reach the ultimate issue of whether the Mylan Defendants' jurisdictional contacts render them "at home" in this forum.

Prior to Daimler, general, all-purpose jurisdiction had long been construed to require only that the defendant have "'continuous and systematic general business contacts'" with the forum state. AFTG-TG, LLC v. Nuvoton Tech. Corp., 689 F3d 1358, 1360 (Fed. Cir. 2012) (quoting LSI Indus. Inc. v. Hubbell

Lighting, Inc., 232 F.3d 1369, 1375 (Fed. Cir. 2000) (quoting Burger King Corp., 471 U.S. at 472-73; Helicopteros Nacionales de Colombia, S.A., 466 U.S. at 414-16)). As a result, pre-Daimler courts routinely found the exercise of general jurisdiction appropriate based upon a foreign corporation's substantial, continuous, and systematic course of business within a particular forum. See, e.g., LSI Indus., Inc. v. Hubbell Lighting, Inc., 232 F.3d 1369, 1374 (Fed. Cir. 2000). Indeed, in ANDA litigation, as here, general jurisdiction traditionally provided the basis to assert jurisdiction over generic drug company defendants. See, e.g., In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig., 693 F. Supp. 2d 409, 421 (D. Del. 2010) (focusing on defendant's "substantial revenue" from Delaware drug sales in upholding general jurisdiction).

In Daimler, however, the Supreme Court rejected as "unacceptably grasping" an approach to finding general jurisdiction wherein a corporation merely "engages in a substantial, continuous, and systematic course of business" in the forum state, thereby substantially curtailing the application of general jurisdiction over corporate defendants. See Daimler, 134 S. Ct. at 758-62.

Specifically, in Daimler, 22 Argentinian residents filed a complaint in the Northern District of California against a

German manufacturer of luxury vehicles, DaimlerChrysler Aktiengesellschaft (hereinafter, "Daimler"), alleging that Daimler's Argentinian subsidiary collaborated with Argentinian security forces to commit human rights violations during Argentina's "'Dirty War.'" Daimler, 134 S. Ct. at 751-52. Although the plaintiffs acknowledged that Daimler had no ostensible involvement in the Argentina-based allegations, the plaintiffs nevertheless alleged that Daimler should be held "vicariously liable" for its Argentinian subsidiary's "alleged malfeasance." Id.

In filing the suit in California, the plaintiffs further insisted that California courts could exercise jurisdiction over Daimler for "any and all claims," in light Daimler's agency relationship with its "indirect subsidiary," Mercedes-Benz USA, LLC (hereinafter, "MBUSA"). Id. at 752. MBUSA, Daimler's exclusive importer and distributor in the United States, existed under the laws of Delaware and had its principal place of business in New Jersey. See id. at 751-52. Nevertheless, MBUSA's annual sales of Daimler vehicles in California generated approximately \$4.6 billion in revenues—2.4% of Daimler's global sales—and MBUSA maintained several corporate facilities in the state. See id. at 751-52, 758; see also id. at 766-67 (Sotomayor, J., concurring).

Daimler's own contacts with California, by contrast, remained "sporadic." Id. at 758. Despite the limited nature of Daimler's contacts, the plaintiffs argued that MBUSA's California contacts could be attributed to Daimler, MBUSA's alleged principal, for jurisdictional purposes. See id. at 751-52. Daimler moved to dismiss for want of personal jurisdiction, and the District Court dismissed the plaintiffs' complaint, finding that MBUSA did not qualify as Daimler's agent and that Daimler's own contacts failed to support an exercise of general jurisdiction over Daimler in California. See id. at 752. The Court of Appeals for the Ninth Circuit, however, ultimately reversed on rehearing, finding that Daimler "purposefully and extensively interjected itself into the California market through MBUSA." Bauman v. DaimlerChrysler Corp., 644 F.3d 909, 925 (9th Cir. 2011).

The Supreme Court thereafter granted certiorari on the issue of whether, consistent with due process, Daimler could be held "amenable to suit in California for claims involving only foreign plaintiffs and conduct occurring entirely abroad." Id. at 753. In a unanimous holding, the Supreme Court reversed the Ninth Circuit.⁷ See id. at 758-62. As relevant here, the Supreme Court concluded that "Daimler's slim contacts" with

⁷ Justice Sotomayor filed a concurrence, agreeing with the Supreme Court's ultimate judgment, but for different reasons. Daimler, 134 S. Ct. at 763-773.

California "hardly" rendered it at home in the forum, even if the Court assumed that MBUSA's contacts could be "imputable to Daimler." Id. at 760.

In so concluding, the Daimler Court clarified, in the context of a suit in California for claims involving only foreign plaintiffs and conduct occurring only abroad, that the applicable inquiry for purposes of general jurisdiction "is not whether a foreign corporation's in-forum contacts can," in some sense, be considered "'continuous and systematic." Id. at 761 (citation omitted). Rather, the operative inquiry is "whether that corporation's 'affiliations with the State are so "continuous and systematic" as to render [it] essentially at home in the forum state.'" Id. at 761 (quoting Goodyear, 131 S. Ct. at 2851) (alteration in original). As a result, the Supreme Court explained that a defendant's "place of incorporation and principal place of business" constitute the paradigm, and seemingly exclusive, bases for finding a corporate defendant "at home." Id. at 760. The Supreme Court found that the simplicity of restricting general jurisdiction to these affiliations promoted predictability, by allowing corporations "to structure their primary conduct with some minimum assurance as to where that conduct will and will not render them liable to suit," all while affording "plaintiffs recourse to at least one clear and

certain forum in which a corporate defendant may be sued on any and all claims."⁸ Id. at 760-62.

Nevertheless, the Daimler Court left open the possibility that, in an "exceptional" case, "a corporation's operations in a forum other than its formal place of incorporation or principal place of business may be so substantial and of such a nature as to render the corporation at home in that State." Id. at 761 n.19. An evaluation of the substantiality of a foreign corporation's operations under such circumstances, however, "calls for an appraisal of a corporation's activities in their entirety, nationwide and worldwide," because a corporation simply operating in multiple forums could "scarcely be deemed at home in all of them." Id. at 762 n.20. With respect to Daimler, however, the Court found its "activities in California plainly" insufficient to approach that level, because California did not serve as Daimler's or MBUSA's state of incorporation or their principal place of business. Id. Nor could Daimler reasonably have expected that it would be hailed into California court on an "Argentina-rooted case." Id. at 761.

In relying upon Daimler, Mylan overstates its square application to the nuanced jurisdictional issue presented in the pending motion. Indeed, the factual and legal contexts of this

⁸ By contrast, the Supreme Court suggested that "exorbitant" theories of general jurisdiction would spawn "unpredictability," by rendering a corporation potentially liable to suit for all claims in many if not all states. Id. at 761-62.

litigation could hardly be more different than those addressed in Daimler. Most fundamentally, the Daimler case involved foreign plaintiffs from Argentina suing a foreign defendant from Germany based upon conduct that occurred entirely in Argentina. Given these circumstances, the Supreme Court readily concluded that Daimler could "scarcely" have predicted that it would be subjected to the general jurisdiction of California. See, e.g., id. at 761-62 (describing Daimler as an "Argentina-rooted case," involving "claims by foreign plaintiffs having nothing to do with anything that occurred or had its principal impact in California"). Here, by contrast, each Mylan Defendant has specific, undisputed contacts with this forum and an intention to market generic aripiprazole throughout the United States, including in this forum; and, at the time Mylan provided Otsuka with notice of its ANDA submission, Mylan had already filed related Abilify® ANDA litigation in this District. In that regard, this litigation concerns primarily domestic corporations and their domestic patent dispute, including Mylan's ANDA application to market a generic version of Otsuka's Abilify®, a factual predicate far more related to domestic and forum interests and activities than that addressed by the Supreme Court in Daimler.

Nevertheless, the Court cannot ignore that in Daimler the Supreme Court expressed itself in broad language, and that the

factual circumstances of this litigation satisfy neither of the paradigmatic scenarios for "at home" general jurisdiction under Daimler. Indeed, none of the Mylan Defendants constitute New Jersey corporations, nor does New Jersey serve as their principal place of business. Moreover, although Daimler left open "the possibility" that a foreign corporation's operations may, in an exceptional case, be of a sufficient nature "to render the corporation at home in that State" id. at 761 n.19, the record in this instance remains unclear as to whether the Mylan Defendant's contacts rise to a sufficiently substantial level.

Critically, in arguing that the Mylan Defendants are "at home" in New Jersey, Otsuka principally relies upon the Mylan Defendants' fractional revenue generation in New Jersey, "frequent" litigation in this District, in addition to the physical presence of various Mylan subsidiaries in this State. (See, e.g., Otsuka's Sur-reply at.) These contacts, however, do not appear the functional equivalent of incorporation or principal place of business, nor do they unequivocally demonstrate the requisite operations of the Mylan Defendants within this State. See, e.g., In re Asbestos Prods. Liability Litig. (No. VI), 2014 WL 5394310, at *3 (E.D. Pa. Oct. 23, 2014) (noting that "an 'exceptional case' authorizing general jurisdiction is one in which the defendant's forum contacts are

so pervasive that they may substitute for its place of incorporation or principal place of business") (citing Monkton Ins. Servs., Ltd. v. Ritter, 13-50941, ___ F.3d ___, 2014 WL 4799716, at *2 (5th Cir. Sept. 26, 2014) (finding that it is "incredibly difficult to establish general jurisdiction in a forum other than the place of incorporation or principal place of business"))).

Nevertheless, because the Court finds, as stated below, that Mylan Inc. and Mylan Pharma consented to this Court's jurisdiction, the Court need not determine whether this litigation constitutes an "exceptional case" in which any one of the Mylan Defendants should be deemed "at home" in New Jersey. But see Eli Lilly & Co. v. Mylan Pharmaceuticals, Inc., Civil Action No. 14-389 (S.D. Ind. March 12, 2015) (finding Mylan not "'at home'" in Indiana); Acorda Therapeutics, Inc., ___ F. Supp. 3d ___, 2015 WL 186833, at *7 (finding Mylan not "'at home' in Delaware" under Daimler, based upon nearly-identical allegations); AstraZeneca, ___ F. Supp. 3d ___, 2014 WL 5778016, at *3 (same); AstraZeneca AB v. Mylan Pharma., Inc., No. 14-696, 2014 WL 5780213, at *3-*4 (D. Del. Nov. 5, 2014) (same).⁹ Therefore, the Court turns to the parties' positions concerning consent-by-registration.

⁹ On December 17, 2014, Judge Gregory M. Sleet certified an interlocutory appeal of the post-Daimler personal jurisdiction issue in the context of the AstraZeneca ANDA litigation, and the

2. Mylan Inc. and Mylan Pharma Consented to Personal Jurisdiction in this District by Registering to do Business in New Jersey

Otsuka alternatively argues that the Court may exercise general jurisdiction over Mylan Inc. and Mylan Pharma, given their registration to do business in New Jersey, and appointment of a registered agent for service of process in New Jersey.¹⁰

Federal Circuit recently granted interlocutory review. See AstraZeneca AB v. Mylan Pharmaceuticals Inc., App. No. 2015-117 (Fed. Cir. Mar. 17, 2015). On January 14, 2015, Chief Judge Leonard P. Stark then "wholeheartedly agree[d] with Judge Sleet that the existence of personal jurisdiction in an ANDA case in a post-Daimler world is an important question of first impression that will be (and has been) raised in many pending ANDA cases," thereby requiring additional direction from the appellate courts. Acorda Therapeutics, Inc., 2015 WL 186833. This Court joins those District Courts in concluding that this complicated, post-Daimler question of personal jurisdiction calls out for clarification, particularly because the literal application of Daimler in ANDA litigation may enable generic defendants with sizable revenues in a forum to avoid the forum's personal jurisdiction, and may invite piecemeal litigation of large, related ANDA cases. The present constellation of 24 cases testing the remaining Otsuka patents with regard to defendants' ANDA applications is most instructive. If all ANDA applicants having both their principal place of business and their place of incorporation outside New Jersey were dismissed for lack of personal jurisdiction, the alternative would become numerous duplicative ANDA suits in a dozen or more other courts about the same patents and pharmaceuticals, multiplying the complexity and uncertainty.

¹⁰ At the outset, the Court rejects Otsuka's position that the Mylan Defendants prior litigation activity, and "admission" of personal jurisdiction, constitutes "consent" for purposes of this action. (See, e.g., Otsuka's Opp'n at 12.) In that regard, the Court agrees with the Mylan Defendants that, "'consent to jurisdiction in one case ... extends to that case alone.'" (Mylan's Reply at 4 (quoting Klinghoffer v. S.N.C. Achille Lauro Ed Altri-Gestione Motonave Achille Lauro in Amministrazione Straordinaria, 937 F.2d 44, 50 (2d Cir. 1991)); see also Mallinckrodt Med., Inc. v. Sonus Pharms., 989 F. Supp. 265, 271 (D.D.C. 1998). Nevertheless, Mylan's prior litigation

(Otsuka's Opp'n at 13-14.) The Mylan Defendants, however, challenge the viability of a consent-by-registration theory of personal jurisdiction on two principal grounds. (See Mylan's Reply at 6-9.) Mylan first insists that "the consent-by-registration theory for general jurisdiction cannot survive in a post-International Shoe Co. v. Washington world." (Id. at 6-7.) Mylan then relatedly claims that any "consent-by-registration argument cannot be squared" with Daimler. (Id. at 8.)

The Court, however, need not belabor Mylan's arguments, because it cannot be genuinely disputed that consent, whether by registration or otherwise, remains a valid basis for personal jurisdiction following International Shoe and Daimler. Indeed, International Shoe itself clearly reflects that the Supreme Court's jurisdictional determinations related to cases where "no consent to be sued or authorization to an agent to accept service of process has been given." See Int'l Shoe Co., 326 U.S. at 317. Moreover, the Supreme Court has specifically concluded, on two separate occasions, that a corporation's appointment of an agent for service of process constitutes, under certain

infers, as stated below, some level of contact, even if insufficient for "at home" purposes, with this District. More importantly, current cases in which Mylan invokes this Court's jurisdiction for its own claims strengthen the notion that Mylan can hardly be surprised, much less offended, by Otsuka's assertion of personal jurisdiction. See, e.g., Mylan Inc. v. Apotex Inc., Civil Action No. 14-4560 (MAS/LHG); Mylan Pharma., Inc. v. Celgene Corp., Civil Action No. 14-2094 (ES/MAH). In such cases, Mylan currently invokes the District of New Jersey's jurisdiction, rendering its present argument more puzzling.

circumstances, consent to the forum's personal jurisdiction. See, e.g., Pa. Fire Ins. Co. of Phila. v. Gold Issue Mining & Milling Co., 243 U.S. 93, 95 (1917) (finding that a corporation consented to personal jurisdiction in Missouri by appointing an agent for service under a Missouri statute); Neirbo Co. v. Bethlehem Shipbuilding Corp., 308 U.S. 165 (1939) (finding that the defendant corporation waived its right to contest venue in federal court in New York, by complying with a New York State statute that required it to designate an agent for service of process).

Indeed, in Pa. Fire Insurance Co., the Supreme Court expressed "little doubt" that a foreign corporation's appointment of an agent for service of process suffices for personal jurisdiction purposes, where the statute itself might "rationally be held to go to that length." 243 U.S. at 95. In Robert Mitchell Furniture Co. v. Selden Breck Const. Co., 257 U.S. 213 (1921), the Supreme Court then confirmed that "secur[ing] local jurisdiction in respect of business transacted within the State" served as the primary purpose of requiring the appointment of an in-state agent for service. Id. at 215. In so concluding, the Supreme Court emphasized that, in appointing an agent, a foreign corporation "takes the risk of the construction that will be put upon the statute and the scope of the agency by the State Court." Id. at 216. In that regard,

the Robert Mitchell Furniture Co. Court made clear that a registration statute may suffice to establish jurisdiction, provided that the state's own construction of its statute supports such a broad interpretation. See id.

Nor does the fact that these decisions predated International Shoe compel any contrary conclusion. Indeed, the Supreme Court has never explicitly overruled the holdings of either case, and in the absence of such declaration, the Supreme Court directs the continued application of its precedents. See Eberhart v. United States, 546 U.S. 12, 14-15, 19-20 (2005) (noting that it was a "prudent course" for a lower court to apply prior Supreme Court precedent that had not been expressly overruled); Rodriguez de Quijas v. Shearson/Am. Exp., Inc., 490 U.S. 477, 484 (1989) (urging lower courts to follow Supreme Court precedent that "has direct application in a case"). Moreover, at least one Court of Appeals has expressly recognized the continued vitality of this line of decisions. See, e.g., King v. Am. Family Mut. Ins. Co., 632 F.3d 570, 576 n.6 (9th Cir. 2011). Therefore, this argument too lacks merit.

Nor can the Court find any support for Mylan's position that Daimler, in essence, precludes general jurisdiction by consent, requiring instead that it be limited to a "corporation's place of incorporation and principal place of business" or, in exceptional circumstances, an equivalent forum

in which the corporation could be found "at home." (Mylan's Br. at 8-9.) Indeed, Daimler in its entirety contains but one fleeting reference to the concept of jurisdiction by consent, and this limited reference served only to distinguish between traditional "consensual" jurisdiction and the "non-consensual bases for jurisdiction" addressed in the decision, rather than to cast any doubt on the continued vitality of consent-based jurisdiction. Acorda Therapeutics, Inc., 2015 WL 186833, at *12 (rejecting Mylan's argument that Daimler, in effect, crowded out consent-based jurisdiction); see also Forrest Labs., 2015 WL 880599, at *13 (concluding that Daimler mentions "consent to jurisdiction" in a manner "that hurts, not helps, Mylan's argument").

Moreover, though the Federal Circuit has not yet addressed the consent-by-registration theory of personal jurisdiction, this Court cannot ignore that the majority of federal Courts of Appeals to have considered the question have concluded that compliance with registration statutes may constitute consent to personal jurisdiction.

In Bane v. Netlink, Inc., for example, the Third Circuit explained that, "[b]y registering to do business in Pennsylvania, [the defendant] 'purposefully avail[ed] itself of the privilege of conducting activities within the forum State, this invoking the benefits and protections of its laws.'" 925

F.2d 637, 640 (3d Cir. 1991) (quoting Burger King Corp., 471 U.S. at 475). As a result, the Bane court found the defendant corporation's authorization to do business in Pennsylvania amounted to "consent to be sued in Pennsylvania courts," because the state statute required the defendant to designate the Secretary of the Commonwealth as its agent for service of process "in any action against it." 925 F.2d 637, 640 (3d Cir. 1991) (internal quotation marks and citation omitted).¹¹ In Knowlton v. Allied Van Lines Inc., the Eighth Circuit similarly concluded, based upon the text of a Minnesota state statute and its interpretation by the Supreme Court of Minnesota, that appointment of an agent for service of process conferred "consent to the jurisdiction of Minnesota courts for any cause of action, whether or not arising out of activities within the state." 900 F.2d 1196, 1199-1200 (8th Cir. 1990). Finally, in

¹¹ The Pennsylvania statute specifically stated that a foreign corporation qualified as a "foreign corporation under the laws of [the State]" then this "shall constitute a sufficient basis of jurisdiction to enable the tribunals of this Commonwealth to exercise general personal jurisdiction over such person[.]" Bane, 925 F.2d at 640 (internal quotation marks and citations omitted). The breadth of the Pennsylvania statute admittedly exceeds that of the New Jersey statute, particularly to the extent the Pennsylvania statute explicitly states that registration enables the Pennsylvania state courts "to exercise general personal jurisdiction" over registrants. Nevertheless, the "difference between the wording of the Pennsylvania and New Jersey statutes is not determinative," Sadler v. Hallsmith SYSCO Food Servs., No. 08-4423, 2009 WL 1096309, at *2 (D.N.J. 2009), particularly given the New Jersey state court's broad interpretation of its own statute. See id.

Holloway v. Wright & Morrissey, Inc., the First Circuit found it "well-settled that a corporation that authorizes an agent to receive service of process in compliance with the requirements of a state statute, consents to the exercise of personal jurisdiction in any action" within the scope of the agent's authority. 739 F.2d 695, 697 (1st Cir. 1984). As a result, the Court found a "natural reading" of the New Hampshire statute demonstrated that the defendant consented to personal jurisdiction.¹² Id.

Taken together, these precedents provide clear confirmation that designation of an in-state agent for service of process in accordance with a state registration statute may constitute consent to personal jurisdiction, if supported by the breadth of the statute's text or interpretation. See, e.g., Forrest Labs.,

¹² Two other Circuits have similarly confirmed that viability of consent-by-registration jurisdiction, but ultimately concluded that the relevant state court precedent did not, standing alone, subject foreign corporations to the jurisdiction of the relevant state. See, e.g., King, 632 F.3d at 576-78 (finding no jurisdiction where the Montana Supreme Court specifically limited the reach of the relevant statute to the contacts of foreign corporations in the state); Wenche Siemer v. Learjet Acquisition Corp., 966 F.2d 179, 180-81 (5th Cir. 1992) (holding that the defendant's appointment of an agent for service of process pursuant to a Texas state statute did not amount to consent to personal jurisdiction in Texas "on any dispute with any party anywhere concerning any matter" because "[n]o Texas state court decision has held that this provision acts as a consent to jurisdiction over a corporation in a case such as ours—that is where plaintiffs are nonresidents and the defendant is not conducting substantial activity within the state").

2015 WL 880599, at *6 (citing King v. Am. Family Mut. Ins. Co., 632 F.3d 570, 576 n.6 (9th Cir. 2011)).

Therefore, the Court finds Mylan's arguments concerning consent-by-registration without merit. Indeed, sister district court recently addressed and rejected Mylan's identical arguments in connection with registration statutes in Delaware. See generally Forest Labs., Inc., 2015 WL 880599, at *6. Moreover, based upon Bane, Knowlton, Holloway, and the New Jersey state court's own interpretation of the scope of New Jersey's registration statute, the Court finds ample support to conclude that Mylan Inc.'s and Mylan Pharma's compliance with the relevant registration statute amounted to consent to personal jurisdiction.

Indeed, the State of New Jersey's registration statute in this instance requires that "every foreign corporation authorized to transact business" in the State of New Jersey "continuously maintain a registered office" and "a registered agent having a business office identical with such registered office." N.J.S.A. § 14A:4-1(1). The statute, in turn, provides that "[e]very registered agent shall be an agent of the corporation ... upon whom process against the corporation may be served." N.J.S.A. § 14A:4-2(1).

Mylan Inc. and Mylan Pharma concede that they complied with the State of New Jersey's registration requirements (see Tighe

Dec. at ¶ 8), including maintaining a registered agent in the State for purposes of service of process.¹³ (See Exs. F & G to Otsuka's Opp'n (identifying Mylan Inc.'s and Mylan Pharma's registered agent as "Corporate Service Company 830 Bear Tavern Road, West Trenton, NJ, 08628").) Moreover, the only New Jersey state court that appears to have addressed the breadth of New Jersey's registration statute had little "hesitation" in concluding that the "designation of an agent for the service of process under N.J.S.A. 14A:4-1 amounted to a consent by defendant to be sued in the state courts of New Jersey..."

Litton Indus. Sys., Inc. v. Kennedy Van Saun Corp., 283 A.2d 551, 556 (N.J. Super. Ct. Law Div. 1971), and numerous courts in this district have reached an identical result. See Sadler v. Hallsmith SYSCO Food Servs., No. 08-4423, 2009 WL 1096309 (D.N.J. 2009) (finding that because defendant conceded that it "registered to do business in New Jersey and ha[d] a registered agent for service of process in New Jersey ... [that defendant] consented to being sued in New Jersey"); Randolph Labs. v. Specialties Dev. Corp., 62 F. Supp. 897, 898-99 (D.N.J. 1945) (finding, under the Supreme Court's decision in Neirbo, that defendant corporation's designation of an agent for service of process in conformity with N.J.S.A. § 14:5-3 (now, N.J.S.A. §

¹³ Mylan Labs, by contrast, has not complied with New Jersey's registration statute, and therefore the Court cannot conclude that Mylan Labs consented to the general jurisdiction of this forum.

14A:4-2) constituted "consent" to be sued in a federal court in the State of New Jersey); Da Cunha v. Grasselli Chem. Co., 46 F. Supp. 28, 29 (D.N.J. 1942) (same).

Here, the Court finds that Mylan Inc. and Mylan Pharma consented to the Court's jurisdiction by registering to do business in New Jersey, by appointing an in-state agent for service of process in New Jersey, and by actually engaging in a substantial amount of business in this State.¹⁴ (See Tighe Dec. at ¶¶ 7-11 (noting that Mylan Inc. and Mylan Pharma are licensed to do business in this jurisdiction, maintain registered agents

¹⁴ For that reason, the Court rejects Mylan's reliance upon Agbottah v. Orange Lake Country Club, No. 12-1019, 2012 WL 2679440, at *3 (D.N.J. July 6, 2012); Smith v. S&S Dundalk Eng'g Works, Ltd., 139 F. Supp. 2d 610, 620 (D.N.J. 2001); Kubin v. Orange Lake Country Club, Inc., No. 10-1643, 2010 WL 3981908, at *3 (D.N.J. Oct. 8, 2010), Atkinson & Mullen Travel Inc. v. N.Y. Apple Tours Inc., No. 97-4460, 1998 WL 750355, at *2 (D.N.J. Sept. 16, 1998), and Ratliff v. Cooper Labs., Inc., 444 F.2d 745, 748 (4th Cir. 1971), because in each case the courts found a certificate to do business in New Jersey insufficient to confer general jurisdiction, given the absence of any evidence that the corporate defendant did indeed conduct business in New Jersey. See, e.g., Ratliff, 444 F.2d at 748 (noting that "due process require[s] a firmer foundation" that merely applying "for the privilege of doing business"); Agbottah, 2012 WL 2679440, at *3-*4 (finding the defendant's registration and solicitation of business insufficient, where the plaintiffs did not allege a volume of business, nor did "they describe any agents, property, records, or other contacts" the defendant "maintains in New Jersey"). Here, by contrast, Mylan Inc. and Mylan Pharma concede that their New Jersey-activities extend far beyond mere registration or solicitation of business. (See generally Tighe Dec.) Indeed, both entities derive significant revenue from New Jersey (see id. at ¶ 11; see also Tighe Supplemental Dec. at ¶ 2), maintain active agents within the State, solicit participants for clinical trials, and seek an obtain Medicaid reimbursements with this forum.

in this jurisdiction, and generate very sizable revenues from sales in this jurisdiction); see also Exs. H, I, and J to Otsuka's Opp'n (demonstrate that Mylan Inc. and Mylan Pharma actively recruited participants for drug studies in New Jersey).)

Nevertheless, because Mylan Labs has not similarly complied with New Jersey's registration statute, the Court turns to whether the Court may exercise specific jurisdiction over Mylan Labs.

3. The Court Lacks Specific Jurisdiction over Mylan Labs

Otsuka does not focus upon the grounds on which the Court could conceivably exercise specific jurisdiction over Mylan Labs, Mylan Inc.'s Indian subsidiary. (See, e.g., Otsuka's Br. at 9-12; Otsuka's Sur-reply at 11.) Rather, Otsuka primarily hinges its position upon Mylan's integrated nature, the international scope of Mylan Labs' operations, and the in-state activities of its independent subsidiary. (See, e.g., Compl. at ¶ 9.) Otsuka, however, identifies no specific activities directed at this forum that, in any way, relate to Otsuka's infringement claims. For that reason, the Court readily rejects Otsuka's position that the Court possesses specific jurisdiction over Mylan Labs.

Critically, in evaluating the existence of specific jurisdiction, the Federal Circuit directs district courts to

consider: (1) whether the defendant purposefully directed activities at residents of the forum; (2) whether the claim arises out of or relates to those activities; and (3) whether, given the circumstances, the assertion of personal jurisdiction would be reasonable and fair. See, e.g., AFTG-TG, LLC, 689 F.3d at 1361. Here, however, Mylan Labs would appear to have no appreciable connection to the alleged infringement issues that give rise to this action. Moreover, Otsuka has not alleged, nor demonstrated, that Mylan Labs itself purposefully directed any relevant claims-based contact towards this forum.¹⁵ Nor has Otsuka provided any basis, much less addressed the relevant standard, to impute the alleged jurisdictional contacts of Mylan Labs' subsidiaries to Mylan Labs itself for purposes of specific jurisdiction in this litigation. Therefore, Mylan Labs will be dismissed for lack of personal jurisdiction.

¹⁵ As a result, the Court need not reach the issue of whether future intent to distribute serves as a sufficient forum-related contact for purposes of specific jurisdiction. The Court notes, however, that the one district court in this Circuit to have addressed this issue, AstraZeneca, ___ F. Supp. 3d ___, 2014 WL 5778016, at *3, found such future intent sufficient for jurisdictional purposes principally as a result of the fact that the generic defendant mailed its paragraph IV letter to the brand name plaintiff in New Jersey. See generally id. No such similar contact has been alleged in this instance, nor does Mylan Labs appear to have participated, at all, in the submission of Mylan Pharma's ANDA.

V. CONCLUSION

For all of these reasons, Mylan's motion to dismiss will be denied as to Mylan Inc. and Mylan Pharma, and granted as to Mylan Labs. An accompanying Order will be entered.

March 23, 2015

Date

s/ Jerome B. Simandle

JEROME B. SIMANDLE

Chief U.S. District Judge